

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 15616PCT00 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEAA416) | |
| International application No. PCT/DK 03/0927 | International filing date (day/month/year) 19.12.2003 | Priority date (day/month/year) 20.12.2002 |
| International Patent Classification (IPC) or both national classification and IPC C08J7/04, C08K5/00, C09D139/06, A61L29/14 | | |
| Applicant COLOPLAST AS | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

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| Date of submission of the demand 13.07.2004 | Date of completion of this report 03.03.2005 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 | Authorized Officer Hallemeesch, A Telephone No. +31 70 340-2431  |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 03/00927**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-20 as originally filed

Claims, Numbers

1-10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-9 |
| | No: Claims | 10 |
| Inventive step (IS) | Yes: Claims | 1-9 |
| | No: Claims | 10 |
| Industrial applicability (IA) | Yes: Claims | 1-10 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK 03/00927

1). State of the art

Reference is made to the following documents :

D1 : WO-9005162A

D2 : US2002/045049A

D3 : WO-9858990A

D1 discloses an article such as a plastics catheter having a low-friction surface coating comprising a polyvinylpyrrolidone (claims 1, 7-9). The coating consists of a mixture of polyurethane, polyvinylpyrrolidone (PVP) and at least two solvents of different volatility. The polyvinylpyrrolidone is soluble in the most volatile solvent and only partly soluble in the least volatile solvent (claim 10). Solvent systems may be selected based on the Hansen Solubility Parameters (page 6, lines 4-5). Ethylene carbonate and propylene carbonate are mentioned explicitly (claim 14; examples 23 with regard to example 1).

D2 (examples 1 and 2) as well as D3 (examples 1-6) disclose crosslinking of coating solutions comprising polyvinylpyrrolidone in ethanol/gamma butyrolactone solvent containing a UV catalyst on catheters by exposing to UV light. Gamma butyrolactone has boiling point 204°C (Beilstein).

2). Art. 33(1)(2) PCT - Novelty

Process claim 1 is novel because the curing step is not mentioned in D1 and the plasticizer used in D2 and/or D3 is different from what is claimed in claim 1. For the same reasons are the independent product claims 7 and 8 considered to be novel.

However, the novelty objection with regard to claim 10 of the application is maintained in view of the teachings of D1.

Example 1 of D1 describes on page 7, lines 31-38 a standard composition comprising 4.55% PVP, 82,12% of a good solvent, 12.12 % plasticiser (acetone in example 1, but propylene carbonate in example 23) and 1,21 % of an additive (polyurethane).

The composition of example 23 is very similar to the polymer solution of claim 10. It is also used to prepare a hydrophilic coating, which is, however, not crosslinked because it does not contain a crosslinkable component.

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International application No. PCT/DK 03/00927

It is quite doubtful that the polymer solution of claim 10, when used to prepare a hydrophilic coating, will crosslink at all because no crosslinking component appears to be present either.

Consequently, a technical feature is missing in the present claim 10. Claim 10 is considered to lack novelty and, the provisions of Art. 33(1) PCT, are, therefore, not met.

3). Art. 33(1)(3) PCT - Inventive step

Departing from D2 and/or D3 as closest prior art, it seems unlikely that the skilled person will turn to D1 to solve the technical problem of providing a further coating process, because in this document only one example out of thirty discloses propylene carbonate plasticizer in a coating process without crosslinking.

Consequently, independent claims 1, 7 and 8 are also based on an inventive step. The dependent claims 2-6 and 9 add further technical features to independent claims which are novel and inventive and are, therefore, also novel and inventive.